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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,873

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Javier Ara Pinilla

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EXAMINER

DUFOUR, DEVANIE A

ART UNIT

PAPER NUMBER

3733

MAIL DATE

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12/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,873	Applicant(s) ARA PINILLA ET AL.	
	Examiner DEVANIE DUFOUR	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The measurement "the tubular nail and probe having a length no greater than the distance between the proximal and distal ends of the long bone" is unclear, because long bones vary greatly based on species, age of patient, and location of bone within the body. Claims 2, 3, and 5 are rejected due to dependency on claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aginsky (U.S. Pub. No. 4,227,518) in view of Summerlin et al. (U.S. Pat. No. 3,512,448).

Aginsky discloses an intramedullary nail (Fig. 1), which is specially designed to secure and immobilise fractures in a long bone such as the femur, said long bone having a proximal end, a distal end and an inner wall defining a medullary cavity between the proximal and distal ends (the device of Aginsky is capable of immobilizing fractures in a long bone),

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comprising the functional combination of a support (15, 16, one strip 18), a tubular nail (10) and a probe (12, 13, 14) at least coextensive in length with the nail (Fig. 1) and movable axially inside the nail (column 3, lines 48-56), said tubular nail and probe having a length no greater than the distance between the proximal and distal ends of the long bone (the device of Aginsky has a length which is less than at least one long bone, Fig. 1), said support adapted to engage the proximal end of said long bone and anchor said tubular nail against rotation (Fig. 1, column 4, lines 19-21).

The support (Figs. 1-6, 15, 16, one strip 18) being the only element of the said functional combination that is fixed to the bone prior to actuation of said nail (the support is capable of being fixed to the bone prior to actuation of the nail), said support having a stepped axial hole (Fig. 2) for attachment of the nailhead (15 and 16 attach to 10, column 4, lines 6-21) and a radial fin (one strip 18) oriented radial to the longitudinal axis of said tubular nail (Fig. 6) with a pair of screw holes (32) for screwing the support to the bone. In combination with an intramedullary nail a template (Figs. 1-6, another strip 18) with guideways (32) for drilling into the proximal end of the bone prior to actuation of said intramedullary nail (the holes 32 of Aginsky allow for drilling into the bone prior to action of the nail), characterised in that inside the axial hole in the support (axial hole of 15 and 16) at the outer end thereof, there is a threaded section (internal threaded section of 16) for the attachment of a said template for drilling into the bone (the template is capable of attaching to support 15 and 16), which is when said guideways are situated in line with the said screw holes (the guideways 32 of one strip 18 are in line with the screw holes 32 another strip 18). The probe (Figs. 1-7, 12, 13, and 14) has a threaded rod (14) extending through and beyond said nailhead and said support (the rod extends though and

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beyond the nailhead and the support), said intramedullary nail including a collar (41) threaded into said rod and operable during actuation of said intramedullary nail to be rotated to displace said rod and said probe in order to displace the protrusion thereon towards said nailhead (column 4, lines 59-67 column 5 lines 1-4).

Aginsky discloses the claimed invention except for said tubular nail including a nailhead, a plurality of thin rods of a considerable length extending from said head and having an intermediate node, said rods being grouped according to an imaginary cylindrical surface and converging towards the node independent at their free ends, said probe including a protrusion close to its distal end, which is adapted to initially extend beyond the tubular nail and upon withdrawal to within the tubular nail, causes the radial deformation of the terminal section of the rods during the axial withdrawal of the probe through the nail and then causes the node to move towards the nailhead which in turn causes a radial expansion of the tubular nail in the proximal area of the rods between said nailhead and said node, said expansion affixing said tubular nail to said inner wall. Aginsky disclose the tubular nail (10) can be expanded via expander body (12 and 13) in order to grip the inside of the cavity walls of one bone end (abstract). Summerlin et al. (Figs. 1-3) discloses said tubular nail (11) including a nailhead (28), a plurality of thin rods (17 and 21) of a considerable length extending from said head (Fig. 2) and having an intermediate node (18), said rods being grouped according to an imaginary cylindrical surface (Fig. 1) and converging towards the node (Fig. 2, rods converge toward 18) independent at their free ends (rods independent near ref. 14), said probe (12 and 14) including a protrusion (14) close to its distal end, which is adapted to initially extend beyond the tubular nail (Fig. 1) and upon withdrawal to within the tubular nail (Fig. 3), causes the radial deformation of the terminal

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section of the rods during the axial withdrawal of the probe through the nail (Fig. 3, 17 deformed) and then causes the node (18) to move towards the nailhead which in turn causes a radial expansion of the tubular nail in the proximal area of the rods between said nailhead and said node (Fig. 3, 21 is deformed), said expansion affixing said tubular nail to said inner wall (Fig. 3). Summerlin et al. disclose the configuration of the fastener in order for the expansible part to grip the wall of the hole, and in order for the sleeve-like member not to exert substantial thrust on the head member which would tend to reduce the clamping of the head member against the surface (column 1, lines 33-63). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the nail body and expander body of Aginsky with the nail body and wedge of Summerlin et al. in order for the expansible part to grip the wall of the hole, and in order for the sleeve-like member not to exert substantial thrust on the head member which would tend to reduce the clamping of the head member against the surface (column 1, lines 33-63).

Response to Arguments

Applicant's arguments filed September 15, 2009 have been fully considered but they are not persuasive.

Applicant argues that Summerlin et al. does not disclose an intramedullary nail, which is specifically designed to secure and immobilize fractures in long bones. The Examiner respectfully disagrees with applicant's arguments because the devices of Summerlin et al. is capable of securing and immobilizing fractures. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims

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distinguishable over Summerlin et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See form 892.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVANIE DUFOUR whose telephone number is (571)270-7843. The examiner can normally be reached on Mon-Thurs 7:00 a.m.-5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

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